IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD, and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC. Defendants.	C.A. No. 16-cv-00908-SLR
LUPIN LIMITED Counterclaimant, v. ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD, and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC. Counterdefendants.	

DEFENDANTS LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") hereby answer the Complaint of Astellas Pharma, Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs") as follows:

THE PARTIES[1]

1. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint and, therefore, denies each and every allegation in Paragraph 1.

2. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in Paragraph 2 of the Complaint and, therefore, denies each and every allegation in Paragraph 2.

3. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of the Complaint and, therefore, denies each and every allegation in Paragraph 3.

4. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 400 051, India. Lupin admits that Lupin Ltd. develops, manufactures, and seeks regulatory approval for generic pharmaceutical products for the United States market. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 4 of the Complaint.

5. Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware and has its principal place of business at Harbourplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin admits that Lupin Pharmaceuticals, Inc. distributes generic pharmaceutical drug products throughout the United States. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action.

[1] For the Court's convenience, Lupin has incorporated the "Headings" that appear in the Complaint. Lupin, however, does not necessarily agree with the characterizations of such Headings, and does not waive any right to object to those characterizations.

Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 5 of the Complaint.

6. Lupin admits that Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd.

7. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the United States Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of the drug product described therein. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 7 of the Complaint.

NATURE OF THE ACTION

8. Lupin admits that the Complaint filed by Plaintiffs purports to state a civil action for patent infringement arising under the United States patent laws, Title 35, United States Code. Lupin admits that the Complaint alleges infringement of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent"). Lupin admits that the Complaint purports to concern Lupin's filing of ANDA No. 209485 with the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market generic pharmaceutical products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 8 of the Complaint.

JURISDICTION AND VENUE

9. Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this Court has subject matter jurisdiction under 28 U.S.C §§ 1331 and 1338(a) solely for the claims directed against Lupin

Ltd. under 35 U.S.C. § 271(e)(2). Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 9 of the Complaint.

10. Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 10 of the Complaint.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 11 of the Complaint.

12. Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a Delaware corporation. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. To the extent an answer is required, Lupin denies each and every remaining allegation contained in Paragraph 12 of the Complaint.

13. Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products, and that Lupin Pharmaceuticals, Inc. distributes generic pharmaceutical drug products throughout the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 13 of the Complaint.

14. Paragraph 14 of the Complaint contains legal conclusions to which no answer is required. Lupin denies each and every allegation contained in Paragraph 14 of the Complaint.

15. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA under FDCA Section 505(j)(2)(B)(ii), seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of extended release tablets**,** each containing 25 mg or 50 mg mirabegron as the active ingredient ("ANDA Products") prior to the expiration of each of the '117, '049, '474, and '872 patents. Lupin admits that the proposed package insert for Lupin Ltd.'s ANDA Products states that the ANDA Products are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 15 of the Complaint.

16. Lupin admits that Lupin Ltd. sent a letter dated August 25, 2016 to Astellas Pharma Inc. and Astellas Pharma Global Development, Inc., entitled "Notice of Paragraph IV Certification Regarding NDA 202611 (Mirabegron) with respect to U.S. Patent Nos. 7,342,117; 7,982,049; 8,835,474; and RE44,872" ("Notice Letter"). Lupin admits that the Notice Letter is signed by an attorney on behalf of Lupin Ltd. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 16 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 16.

17. Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies each and every allegation contained in Paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this

Court for the purposes of this civil action only. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 18 of the Complaint.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest venue in this Court for the purposes of this civil action only. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 19 of the Complaint.

FACTUAL BACKGROUND

A. The '117 Patent

20. Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the face of the '117 patent, the '117 patent, entitled "α-Form or β-Form Crystal of Acetanilide Derivative," issued on March 11, 2008. Lupin admits that what purports to be a copy of the '117 patent is attached to the Complaint as Exhibit A. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 20 of the Complaint.

21. Paragraph 21 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 21 of the Complaint and, therefore, denies each and every allegation in Paragraph 21.

22. Lupin admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists the expiration date of the '117 patent as November 4, 2023.

B. The '049 Patent

23. Paragraph 23 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the face of the

’049 patent the ’049 patent, entitled “α-Form or β-Form Crystal of Acetanilide Derivative,” issued on July 19, 2011. Lupin admits that what purports to be a copy of the ’049 patent is attached to the Complaint as Exhibit B. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 23 of the Complaint.

24. Paragraph 24 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 24 of the Complaint and, therefore, denies each and every allegation in Paragraph 24.

25. Lupin admits that the Orange Book lists the expiration date of the ’049 patent as November 4, 2023.

C. <u>The ’474 Patent</u>

26. Paragraph 26 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the face of the ’474 patent, the ’474 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative as the Active Ingredient,” issued on September 16, 2014. Lupin admits that what purports to be a copy of the ’474 patent is attached to the Complaint as Exhibit C. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 26 of the Complaint.

27. Paragraph 27 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 27 of the Complaint and, therefore, denies each and every allegation in Paragraph 27.

28. Lupin admits that the Orange Book lists the expiration date of the ’474 patent as November 4, 2023.

D. The ’872 Patent

29. Paragraph 29 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the face of the ’872 patent, the ’872 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative as the Active Ingredient,” reissued on April 29, 2014. Lupin admits that what purports to be a copy of the ’872 patent is attached to the Complaint as Exhibit D. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 29 of the Complaint.

30. Paragraph 30 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 30 of the Complaint and, therefore, denies each and every allegation in Paragraph 30.

31. Paragraph 31 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 31 of the Complaint and, therefore, denies each and every allegation in Paragraph 31.

32. Lupin admits that the Orange Book lists the expiration date of the ’872 patent as November 4, 2023.

E. Myrbetriq®

33. Lupin admits that, according to the FDA’s electronic records, “APGDI” is the holder of New Drug Application (“NDA”) No. 202611 for extended release tablets, 25 mg and 50 mg, containing mirabegron as the active ingredient. Lupin admits that the FDA’s electronic records list June 28, 2012 as the date of approval for NDA No. 202611. Lupin admits that the Orange Book lists the ’117 patent, the ’049 patent, the ’474 patent, the ’872 patent, and U.S.

Patent No. 6,346,532 ("the '532 patent") with respect to NDA No. 202611. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 33 of the Complaint and, therefore, denies each and every allegation in Paragraph 33.

34. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 34 of the Complaint and, therefore, denies each and every allegation in Paragraph 34.

35. Lupin admits that the prescribing information for Myrbetriq®, dated August 2016, states that Myrbetriq® is "indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency[.]" Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 35 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 35.

36. Lupin admits that the electronic records of the PTO identify Astellas Pharma Inc. as the record owner and assignee of the '532, '117, '049, '474 and '872 patents. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 36 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 36.

37. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 37 of the Complaint and, therefore, denies each and every allegation in Paragraph 37.

38. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 38 of the Complaint and, therefore, denies each and every allegation in Paragraph 38.

F. Infringement by Lupin

39. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA under FDCA Section 505(j)(2)(B)(ii), seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of its ANDA Products prior to the expiration of each of the '117, '049, '474, and '872 patents. Lupin admits that the proposed package insert for Lupin Ltd.'s ANDA Products states that the ANDA Products are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 39 of the Complaint.

40. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA under FDCA Section 505(j)(2)(B)(ii), seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of its ANDA Products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 40 of the Complaint.

41. Lupin admits that the Notice Letter, dated August 25, 2016, states that Lupin Ltd. has submitted ANDA No. 209485 to the FDA under FDCA Section 505(j)(2)(B)(ii) in order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Lupin's ANDA Products. Lupin admits that the Notice Letter states that ANDA No. 209485 includes a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '117, '049, '474, and '872 patents, indicating that in the opinion of Lupin Ltd. and to the best of its

knowledge, the claims of each of the '117, '049, '474, and '872 patents are invalid, unenforceable and/or will not be infringed by the manufacture, importation, use, or sale of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 41 of the Complaint.

42. Lupin admits that Lupin Ltd.'s ANDA Products contain mirabegron as the active ingredient. Lupin admits that ANDA No. 209485 includes a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph III, with respect to the '532 patent, indicating that the '532 patent will expire on March 27, 2022 and that Lupin Ltd. does not seek approval of, and will not market, its ANDA Products prior to March 27, 2022. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 42 of the Complaint.

43. Lupin denies each and every allegation contained in Paragraph 43 of the Complaint.

44. Lupin admits that Lupin Ltd. sent the Notice Letter to Astellas Pharma Inc. and Astellas Pharma Global Development, Inc. on or around August 25, 2016 and that Plaintiffs filed the Complaint on October 7, 2016. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 44 of the Complaint.

COUNT I: DIRECT INFRINMGEMENT OF THE '117 PATENT

45. Lupin restates and incorporates by reference its responses to Paragraphs 1-44 of the Complaint as if fully set forth herein.

46. Lupin denies each and every allegation contained in Paragraph 46 of the Complaint.

47. Lupin denies each and every allegation contained in Paragraph 47 of the Complaint.

48. Lupin denies each and every allegation contained in Paragraph 48 of the Complaint.

COUNT II: DIRECT INGRINGMENT OF THE '049 PATENT

49. Lupin restates and incorporates by reference its responses to Paragraphs 1-48 of the Complaint as if fully set forth herein.

50. Lupin denies each and every allegation contained in Paragraph 50 of the Complaint.

51. Lupin denies each and every allegation contained in Paragraph 51 of the Complaint.

52. Lupin denies each and every allegation contained in Paragraph 52 of the Complaint.

COUNT III: DIRECT INFRINGEMENT OF THE '474 PATENT

53. Lupin restates and incorporates by reference its responses to Paragraphs 1-52 of the Complaint as if fully set forth herein.

54. Lupin denies each and every allegation contained in Paragraph 54 of the Complaint.

55. Lupin denies each and every allegation contained in Paragraph 55 of the Complaint.

COUNT IV: INDUCEMENT TO INFRINGE THE '474 PATENT

56. Lupin restates and incorporates by reference its responses to Paragraphs 1-55 of the Complaint as if fully set forth herein.

57. Lupin admits that it presently has knowledge of the '474 patent. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 57 of the Complaint.

58. Lupin denies each and every allegation contained in Paragraph 58 of the Complaint.

59. Lupin denies each and every allegation contained in Paragraph 59 of the Complaint.

60. Lupin denies each and every allegation contained in Paragraph 60 of the Complaint.

61. Lupin denies each and every allegation contained in Paragraph 61 of the Complaint.

62. Lupin denies each and every allegation contained in Paragraph 62 of the Complaint.

63. Lupin denies each and every allegation contained in Paragraph 63 of the Complaint.

64. Lupin denies each and every allegation contained in Paragraph 64 of the Complaint.

COUNT V: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

65. Lupin restates and incorporates by reference its responses to Paragraphs 1-64 of the Complaint as if fully set forth herein.

66. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA under FDCA Section 505(j)(2)(B)(ii) in order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale or sale of its ANDA Products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 66 of the Complaint.

67. Lupin denies each and every allegation contained in Paragraph 67 of the Complaint.

68. Lupin denies each and every allegation contained in Paragraph 68 of the Complaint.

69. Lupin denies each and every allegation contained in Paragraph 69 of the Complaint.

70. Lupin denies each and every allegation contained in Paragraph 70 of the Complaint.

COUNT VI: DIRECT INFRINGEMENT OF THE '872 PATENT

71. Lupin restates and incorporates by reference its responses to Paragraphs 1-70 of the Complaint as if fully set forth herein.

72. Lupin denies each and every allegation contained in Paragraph 72 of the Complaint.

73. Lupin denies each and every allegation contained in Paragraph 73 of the Complaint.

COUNT VII: INDUCEMENT TO INFRINGE THE '872 PATENT

74. Lupin restates and incorporates by reference its responses to Paragraphs 1-73 of the Complaint as if fully set forth herein.

75. Lupin admits that it presently has knowledge of the '872 patent. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 75 of the Complaint.

76. Lupin denies each and every allegation contained in Paragraph 76 of the Complaint.

77. Lupin denies each and every allegation contained in Paragraph 77 of the Complaint.

78. Lupin denies each and every allegation contained in Paragraph 78 of the Complaint.

79. Lupin denies each and every allegation contained in Paragraph 79 of the Complaint.

80. Lupin denies each and every allegation contained in Paragraph 80 of the Complaint.

81. Lupin denies each and every allegation contained in Paragraph 81 of the Complaint.

82. Lupin denies each and every allegation contained in Paragraph 82 of the Complaint.

COUNT VIII: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

83. Lupin restates and incorporates by reference its responses to Paragraphs 1-82 of the Complaint as if fully set forth herein.

84. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA under FDCA Section 505(j)(2)(B)(ii) in order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale or sale of its ANDA Products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 84 of the Complaint.

85. Lupin denies each and every allegation contained in Paragraph 85 of the Complaint.

86. Lupin denies each and every allegation contained in Paragraph 86 of the Complaint.

87. Lupin denies each and every allegation contained in Paragraph 87 of the Complaint.

88. Lupin denies each and every allegation contained in Paragraph 88 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Lupin denies all allegations not specifically admitted herein, and further denies that Plaintiffs are entitled to the judgment and relief requested in Paragraphs A-I of the Complaint or to any other relief.

DEFENSES

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 88 of the Complaint, Lupin sets forth the following defenses. Lupin expressly reserves the right to allege additional defenses as they become known through the course of discovery. Lupin does not intend hereby to assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST DEFENSE-FAILURE TO STATE A CLAIM

1. Plaintiff has failed to state a claim upon which relief may be granted because, *inter alia*, Lupin Pharmaceuticals, Inc. has not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

SECOND DEFENSE – LACK OF SUBJECT MATTER JURISDICTION

2. This Court lacks subject matter jurisdiction over any and all claims asserted against Lupin Pharmaceuticals, Inc. This court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. §§ 271(a)-(c).

THIRD DEFENSE – NON-INFRINGEMENT

3. Lupin does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid,

enforceable claim of the ’117, ’049, ’474, and ’872 patents by the manufacture, use, sale, offer for sale, or importation of the mirabegron products that are the subject of ANDA No. 209485.

FOURTH DEFENSE – INVALIDITY

4. One or more claims of the ’117, ’049, ’474, and ’872 patents is invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, for violating the Recapture Rule, and in view of the defenses recognized in 35 U.S.C. § 282(b).

FIFTH DEFENSE-IMPROPER PARTY

5. Lupin Pharmaceuticals, Inc. is not a proper party to this action.

SIXTH DEFENSE-FAILURE TO STATE AN EXCEPTIONAL CASE

6. The Complaint fails to state a claim for an exceptional case, pursuant to 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4).

SEVENTH DEFENSE-ADDITIONAL DEFENSES

7. Lupin reserves the right to present any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaimant Lupin Limited (“Lupin Ltd.”) brings the following Counterclaims against Plaintiffs/Counterdefendants Astellas Pharma Inc., Astellas Ireland Co., Ltd, and Astellas Pharma Global Development, Inc. (collectively, “Counterdefendants”) for a declaratory judgment that the ’117, ’049, ’474, and ’872 patents are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of Lupin Ltd.’s ANDA Products.

JURISDICTION AND VENUE

1. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

2. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

3. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendants' choice of forum.

4. This is an action based upon an actual controversy between the parties concerning the invalidity and/or noninfringement of the '117, '049, '474, and '872 patents and Lupin Ltd.'s right to continue to seek approval of ANDA No. 209485, and upon approval by the FDA, to manufacture, import, use, market, sell, and offer to sell its ANDA Products in the United States.

5. Lupin Ltd. has been and presently is engaged in the submission of documents to the FDA in order to obtain approval to engage in the commercial manufacture, importation, use, or sale of its ANDA Products. Counterdefendants have alleged that Lupin Ltd.'s ANDA Products infringe, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the '117, '049, '474, and '872 patents.

6. Counterdefendants have filed in this Court an infringement action to enforce the '117, '049, '474, and '872 patents.

7. Lupin Ltd. has denied that it has infringed, continues to infringe, or will infringe, induce infringement of, and/or contribute to the infringement of any valid and enforceable claim of the '117, '049, '474, and '872 patents.

8. Lupin Ltd. has further asserted that the '117, '049, '474, and '872 patents are invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, 112, for violating the Recapture Rule, and in view of the defenses recognized in 35 U.S.C. § 282(b).

9. The ’117, ’049, ’474, and ’872 patents are listed in the Orange Book with respect to Myrbetriq.

10. Lupin Ltd.’s ANDA No. 209485 includes a certification under FDCA § 505(J)(2)(A)(vii), Paragraph IV, with respect to the ’117, ’049, ’474, and ’872 patents, that no valid, enforceable claim of the patents will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 209485 has been submitted. On August 25, 2016, pursuant to § 505(j)(2)(B) of the FDCA, Lupin Ltd. notified Counterdefendants by letter (“Notice Letter”) that Lupin Ltd. filed ANDA No. 209485 with the FDA containing certifications pursuant to FDCA § 505(j)(2)(A)(vii)(IV) that the ’117, ’049, ’474, and ’872 patents are invalid and/or would not be infringed by Lupin Ltd’s ANDA Products.

11. In view of the foregoing, a conflict of asserted rights has arisen between Lupin Ltd. and Counterdefendants with respect to the noninfringement and invalidity of the relevant claims of the ’117, ’049, ’474, and ’872 patents, and as to Lupin Ltd.’s right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of its ANDA products. An actual controversy therefore exists between Counterdefendants and Lupin Ltd.

PARTIES

12. Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 400 051, India.

13. On information and belief, and based on Counterdefendants’ allegations, Counterdefendant Astellas Pharma Inc. is a corporation organized and existing under the laws of

Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

14. On information and belief, and based on Counterdefendants' allegations, Counterdefendant Astellas Ireland Co., Ltd. is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. Astellas Ireland Co. Ltd. is a subsidiary of Counterdefendant Astellas Pharma Inc.

15. On information and belief, and based on Counterdefendants' allegations, Counterdefendant Astellas Pharma Global Development, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. Astellas Pharma Global Development, Inc. is a subsidiary of Counterdefendant Astellas Pharma Inc.

FIRST COUNTERCLAIM – DECLARATION OF PATENT NONINFRINGEMENT

16. Lupin Ltd. realleges Paragraphs 1-15 as though fully set forth herein.

17. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '117, '049, and '872 patents.

18. The sale, offer for sale, manufacture, importation or use of Lupin Ltd.'s ANDA Products will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable claim of the '117, '049, and '872 patents.

19. Lupin Ltd.'s ANDA Products will not infringe at least Claim 2 of the '117 patent, Claims 2-4, 6-8, 10-12, and 14-16 of the '049 patent, and Claims 1-14 of the '872 patent.

20. Lupin Ltd.'s ANDA Products will not infringe at least Claim 2 of the '117 patent at least because the mirabegron in Lupin Ltd.'s ANDA Products does not exhibit at least some of the claimed PXRD peaks.

21. Lupin Ltd. will not directly infringe any method claim of the '049 patent at least because Lupin Ltd. will not administer its ANDA Products to patients. Lupin Ltd. will not indirectly infringe at least Claims 2, 4, 6, 8, 10, 12, 14, and 16 of the '049 patent at least because Lupin Ltd. is not seeking approval of its ANDA Products for the treatment of diabetes. Lupin's Ltd.'s ANDA Products will not infringe at least Claims 3-4, 7-8, 11-12, and 15-16 of the '049 patent at least because Lupin Ltd.'s ANDA Products do not contain the claimed crystal form of mirabegron.

22. Lupin Ltd. will not directly infringe any claim of the '872 patent at least because Lupin Ltd. will not administer its ANDA Products to patients. Lupin Ltd. will not indirectly infringe any claim of the '872 patent at least because the proposed labeling for Lupin Ltd.'s ANDA Products does not encourage, recommend, or promote the use of Lupin Ltd.'s ANDA Products in patients "not suffering from diabetes." Additionally, Lupin Ltd. will not indirectly infringe Claims 13 and 14 of the '872 patent at least because the proposed labeling for Lupin Ltd.'s ANDA Products does not encourage, recommend, or promote the use of Lupin Ltd.'s ANDA Products in non-adult patients "not suffering from diabetes."

23. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, or use of its ANDA Products do not, and would not if marketed, infringe any valid and enforceable claim of the '117, '049, and '872 patents.

SECOND COUNTERCLAIM – DECLARATION OF PATENT INVALIDITY

24. Lupin Ltd. realleges Paragraphs 1-23 as though fully set forth herein.

25. The claims of the '117 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 102, 103, 112, and/or in view of the defenses recognized in 35 U.S.C. § 282(b). The claims of the '117 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Canadian Patent Publication No. CA2305802 to Maruyama et al. ("Maruyama"); U.S. Patent No. 6,346,532 C1 (reexamined) to Maruyama et al. ("Maruyama 2002"); 1987 FDA Guidelines for Drug Applications ("FDA Guidelines"); Fiese, E.F. and Hagen, T.A. in The Theory and Practice of Industrial Pharmacy, Lachman, L. et al., eds., 171-196 (1986) ("Finese"); Haleblian, J. and McCrone, W., J. Pharm. Sci., 58(8):911-29 (1969) ("Haleblian"); Guillory, J.K. in Polymorphism in Pharmaceutical Solids, Brittain, H.G. ed., 183-226 (1999) ("Guillory"); Brittain, H., J. Pharm. Sci., 86:404-412 (1997) (Brittain 1997"); Brittain, H., in Polymorphism in Pharmaceutical Solids, Brittain, H.G. ed., 227-278 (1999) ("Brittain 1999"); Borka, L., Acta Pharm. Jugosl., 40:71-94 (1990) ("Borka"); Cardew, P.T. and Davey, R.J., Proc. R. Soc. Lond. A., 398:415-428 (1985) ("Cardew"); Sato, K., J. Phys. D.: Appl. Phys., 26:B77-B84 (1993) ("Sato"); and/or Remington: The Science and Practice of Pharmacy, Gennaro, A. et al. eds. (29th ed. 2000) ("Remington"); and at least some claims of the '117 patent are invalid at least under 35 U.S.C. § 112 for lack of enablement.

26. The claims of the '049 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 102, 103, 112, and/or in view of the defenses recognized in 35 U.S.C. § 282(b). The claims of the '049 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Maruyama; Maruyama 2002; FDA Guidelines; Fiese; Haleblian; Guillory; Brittain 1997; Brittain 1999; Borka; Cardew; Sato; and/or Remington; and at least

some of the claims of the ’049 patent are invalid at least under 35 U.S.C. § 112 for lack of enablement.

27. The claims of the ’474 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. § 102, 103 and/or in view of the defenses recognized in 35 U.S.C. § 282(b). The claims of the ’474 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Maruyama; Maruyama 2002; Canadian Patent Publication No. CA2398199 to Umeno and Ogawa (“Umeno”); U.S. Patent No. 6,291,491 to Weber et al. (“Weber”); Igawa, Y. et al., Proc. 1997 ICS Annual Meeting, Abstract 14, Neurourol. Urodynamics, 16:363-365 (“Igawa 1997”); Igawa, Y. et al., Acta Physiol. Scand., 164:117-118 (1998) (“Igawa 1998”); Igawa, Y. et al., Brit J. Pharmacol., 126:819-825 (1999) (“Igawa 1999”); Takeda, H. et al., J. Pharmacol. Exp. Therapeutics, 293:939:945 (2000) (“Takeda 2000”); Woods. M. et al., J. Urology, 166:1142-47 (“Woods”); and/or Bosch, J.L.H.R., BJU Int’l, 83(Supp. 2):7-9 (1999) (“Bosch”).

28. The claims of the ’872 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and the defenses recognized in 35 U.S.C. § 282(b). The claims of the ’872 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Maruyama; Maruyama 2002; Umeno; Weber; Igawa 1997; Igawa 1998; Igawa 1999; Takeda 2000; Woods; and/or Bosch; and at least some of the claims of the ’872 patent are invalid at least for violation of the Recapture Rule.

29. Lupin Ltd. is entitled to a judicial declaration that the claims of the ’117, ’049, ’474, and ’872 patents are invalid and unenforceable.

DEMAND FOR JUDGMENT

WHEREFORE, Lupin Ltd. prays for the following relief:

A. That all claims against Lupin be dismissed with prejudice and that all relief requested by Counterdefendants be denied;

B. That a judgment be entered declaring that Lupin Ltd. has not and does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid, enforceable claim of U.S. Patent Nos. 7,342,117; 7,982,049; and RE44,872; that Lupin Ltd. has a lawful right to obtain FDA approval of ANDA No. 209485; and further that Lupin Ltd. has a lawful right to manufacture, import, use, sell, and/or offer to sell its ANDA Products in the United States once approved by the FDA;

C. That a judgment be entered declaring the claims of U.S. Patent Nos. 7,342,117; 7,982,049; 8,835,474; and RE44,872 invalid and unenforceable;

D. That Counterdefendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Lupin or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Lupin, or charging any of them either orally or in writing with infringement of U.S. Patent Nos. 7,342,117; 7,982,049; and RE44,872;

E. That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Lupin Ltd. is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

F. That Lupin Ltd. be awarded costs, attorney’s fees and other relief, both legal and equitable, to which it may be justly entitled; and

G. That Lupin Ltd. be awarded such other and further relief as is just and proper.

Respectfully submitted,

PHILLIPS, GOLDMAN MCLAUGHLIN & HALL, P.A.

Dated: January 17, 2017

By: */s/ John C. Phillips, Jr.*

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